and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product, Allergen Patch Test (Thin-layer Rapid Use Epicutaneous (T.R.U.E.) Test™) (multiple allergen test). T.R.U.E. Test™ is indicated primarily as an aid in the diagnosis of allergic dermatitis in patients whose histories suggest sensitivity to one or more of substances included on the T.R.U.E. Test™ panels. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for T.R.U.E. Test™ (U.S. Patent No. 4,836,217) from Pharmacia AB, and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 21, 1995, FDA advised the Patent and Trademark Office that this human biologic product had undergone a regulatory review period and that the approval of T.R.U.E. Test™ represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for T.R.U.E. Test™ is 2,966 days. Of this time, 1,601 days occurred during the testing phase of the regulatory review period, while 1,365 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective*: October 10, 1986. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on October 10, 1986.

2. *The date application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act*: February 26, 1991. The applicant claims July 16, 1986, as the date the product license application (PLA) for T.R.U.E. Test™ (PLA 91–0118) was initially submitted. However, FDA records indicate that the two-panel test kit for the product that was ultimately approved was submitted on February 26, 1991. Therefore, the PLA was submitted on February 26, 1991.

3. *The date the application was approved*: November 21, 1994. FDA has verified the applicant's claim that PLA 91–0118 was approved on November 21, 1994.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, the applicant seeks 898 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 2, 1995, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 30, 1996, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 26, 1995.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 95–19060 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95F–0187]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidyl)imino] hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino]] as a light stabilizer in polymers used as an indirect food additive.

DATES: Written comments on the petitioner's environmental assessment by September 5, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 5B4467) has been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of poly[[6-[(1,1,3,3-tetramethylbutyl)amino]-s-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidyl)imino] hexamethylene [(2,2,6,6-tetramethyl-4-piperidyl)imino]] as a light stabilizer in polymers used as an indirect food additive.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4 (b)), the

agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before September 5, 1995, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 21, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–19090 Filed 8–2–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0157]

Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species; Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of revised Compliance Policy Guide (CPG) 7108.24, entitled ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species.'' Revised CPG 7108.24 lowers the histamine level at which FDA may consider the fish subject to action under the Federal Food, Drug, and Cosmetic Act (the act) and states that the histamine defect action level (DAL) and the histamine action level (AL) now apply to raw, frozen tuna and mahi-mahi in addition to canned tuna. Furthermore, the revised CPG 7108.24 states that the AL also applies to related species of raw, frozen, and canned fish implicated in instances of histamine poisoning, such as bluefish, amberjack, and mackerel, in addition to tuna and mahi-mahi. Additionally, for these related species, levels of histamine less than the AL may be considered as evidence of decomposition on a case-by-case basis when supported by additional scientific data. The title of the revised CPG reflects these changes.

DATES: Written comments by September 5, 1995.

ADDRESSES: Submit written requests for single copies of CPG 7108.24, ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi and Canned Tuna; and Related Species,'' and Laboratory Information Bulletin no. 3794 to the Director, Office of Constituent Operations, Industry Activities Staff (HFS–565), Food and Drug Administration, rm. 5827, 200 C St. SW., Washington, DC 20204. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on CPG 7108.24, ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species,'' to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of revised CPG 7108.24, ''Decomposition and Histamine—Raw, Frozen Tuna and Mahi-Mahi; Canned Tuna; and Related Species,'' the *Official Methods of Analysis of the Association of Official Analytical Chemists 15th Ed.* (1990), section 977.13, and Laboratory Information Bulletin no. 3794, and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Office of Seafood (HFS–416), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3160.

SUPPLEMENTARY INFORMATION: Histamine is a chemical compound that forms postmortem in the muscle of scombroid fish, such as tuna, and in other species, such as mahi-mahi, by the action of certain bacteria that are common in fish. Bacteria that have the ability to form histamine do so by the decarboxylation of L-histidine, an amino acid found in the fish muscle. The decarboxylation reaction is catalyzed by an enzyme, histidine decarboxylase, produced by the bacteria. Fish species that are particularly vulnerable to the development of histamine are those with high levels of free L-histidine in their muscle tissues. Additional histidine may be released during decomposition and spoilage by proteolysis, whereby the protein structure is degraded, and amino acids are liberated (Ref. 1). The level of histamine produced in scombroid or other histidine-containing fish by these processes serves as an indicator of the decomposition that has occurred. When present at higher levels, histamine represents a health hazard. Therefore, FDA uses histamine to indicate that these fish are adulterated within the meaning of section 402(a)(1) and (a)(3) of the act (21 U.S.C. 342(a)(1) and (a)(3)).

In the fishing industry, decomposition and bacterial histamine production are controlled primarily by the use of low temperature storage (Ref. 2). Significant decomposition and histamine formation can be avoided by good fish handling practices including icing or rapid immersion of the catch in water chilled to -1 °C (30 °F), followed by uninterrupted frozen storage. Under high temperature storage conditions, histamine may form before other indicators of decomposition are evident, especially the odor and appearance of decomposed fish (Ref. 3).

Histamine also may form during low temperature storage conditions. However, in low temperature storage, the rate of histamine formation is slower, and it is usually accompanied by the typical odor of decomposition. Research sponsored by the Department of Health and Human Services has suggested that freezing may be more damaging to histamine-forming bacteria than it is to nonhistamine producing spoilage bacteria (Ref. 4).

Canned fish is frequently prepared from fish preserved by frozen storage before delivery to canneries. These fish are thawed before processing and are subjected to additional handling that may result in histamine levels in canned fish being somewhat higher than the levels observed in raw, freshly caught fish.

Histamine is generally not uniformly distributed in a decomposed fish. A level of less than 50 parts per million (ppm) in one section may accompany a level in excess of 1,000 ppm elsewhere in the same fillet (Ref. 3). The anterior section of an individual fish generally is higher in histamine content than the posterior section, because the intestine, which is located in the forward end, is apparently the major source of the